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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/03/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on April 19, 2006 is acknowledged. Claims 1-3, 8-10 and 12 are pending and under consideration. Claims 7 and 11 have been canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

1. In view of applicants' response the rejection of claim 12 under 35 U.S.C. 112, first paragraph on page 5, paragraph 4 is withdrawn.

2. In view of applicants' response the rejection of claim 11 under 35 U.S.C 102(e) as being anticipated by Kwon on page 4, paragraph 3 is withdrawn.

3. In view of applicants' response the rejections of claim 1-6, 9 and 10 under 35 U.S.C 102(b) as being anticipated by Binder on page 2, paragraph 2 are withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Brin et al (U.S. 2005/0260231 A1) in light of Wikipedia (On line Encyclopedia).

Claims 1-6 and 8-10 are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the steps of administering a therapeutically effective amount of a botulinum toxin to a location of a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from a group consisting of warts, corns, neuromas, hammertoes and bunions, thereby treating the skin disorder.

Brin et al discloses a method for treating a skin disorder to a patient in need thereof, the method comprises a step of locally administering a therapeutically effective amount of botulinum toxin to a neuroblastoma (0158). Wikipedia (http://en.wikipedia.org/wiki/neuromas) defines "neuroma" as any tumor of cells of the nervous system which are categorized by neurinoma, neurofibroma and neuroblastoma. In view of the dictionary definition the examiner has interpreted neuroblastoma to meet the limitation of neuromas. Moreover, Brin et al discloses that the botulinum toxin is administered in an amount of between about 10^{-3} U/kg and about 2,000 U/kg and the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G (0110). Brin et al discloses that the route of administration is subcutaneous or intramuscular injection (0128). Lastly, Brin et al discloses that the method can provide improved patient function including but not limited to reduced pain (0137). In effectively treating a skin disorder, particularly a neuroma, you inherently reduce the size of the skin disorder as well as the inflammation associated with the skin disorder.

5. Claims 1, 5 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. 2004/0087893 A1).

Claims 1 and 5 are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the steps of administering a therapeutically effective amount of a botulinum toxin to a location of a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from a group consisting of warts, corns, neuromas, hammertoes and bunions, thereby treating the skin disorder, wherein the administration is by topical or subcutaneously, wherein the administration is by topical or subcutaneous administration of botulinum toxin. Subsequent claim 12 is drawn to a method for treating a skin disorder to a patient in need thereof, the method comprising the steps of administering a therapeutically effective amount of a botulinum toxin to a location of a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from a group consisting of dermatofibroma, keloid, mole, granuloma and keratose, thereby treating the skin disorder.

Kwon discloses a method of administering a safe and effective amount of botulinum toxin for treating lesions or abnormal skin features, such as pimples, corns, warts, calluses, bunions and keratoses (page 6, section 0077). Moreover, Kwon discloses administering the botulinum toxin via a patch (topical). The instant specification has characterized a therapeutically effective amount as an amount to alleviate a symptom of a skin disorder (page 21), inherently Kwon has administered a therapeutically amount of botulinum toxin.

6. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Gassner et al (U.S. Patent 6,447,787 B1).

Claim 12 is drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the steps of administering a therapeutically effective amount of a botulinum toxin to a location of a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from a group consisting of dermatofibroma, keloid, mole, granuloma and keratose, thereby treating the skin disorder.

Gassner et al discloses a method for treating a skin disorder in a patient in need thereof, the method comprises a step of administering a therapeutically effective amount of botulinum toxin to the scar (keloid) of a patient (Example 2, column 7, lines 31-60). The method of Gassner is the same as the claimed method.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

First (U.S. Patent 6,063,768), which teaches that when botulinum toxin is used in a safe and effective amount will antagonize and therefore decrease or block inflammation.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
6/15/06

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